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December 9, 1999

Docket No. 97N-484S
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Dear Sir or Madam:

I wish to comment on the FDA proposed rule entitled "Suitablility Determination for Donor of Human Cellular and Tissue-Based Products".

I object to the FDA's proposed definition of minimally manipulated because:

- the term minimally is vague and open to subjective, ever changing definitions;
- the term manipulated is also vague and open to subjective interpretation;
- these proposed terms should be eliminated as they add nothing to the proposed rule and have nothing to do with donor suitability.

I object to the FDA's proposed definition of homologous use because:

- homologous is vague and open to subjective interpretation;
- the term "use" infringes on the practice of medicine. How a doctor decides to use a device should not affect how it is regulated.
- the entire term should be eliminated;
- there is a threat to the public health with these tissues to warrant this type of term being used or distinction being made;
- implementation of this term and its subsequent regulation may restrict availability as tissue banks try to comply with new FDA rules.

I use allograft bone tissue in my practice and do not wish its supply to be curtailed through excessive and unnecessary government regulation. I see no added benefit to having these definitions in the proposed rule.

My patients benefit from my use of allograft bone to treat a wide variety of conditions, some of which have no man-made material labeled alternative.

Thank you for the opportunity to comment on this proposed rule.

Sincerely,

Gilbert R. Meadows, M.D.

GRM/dg

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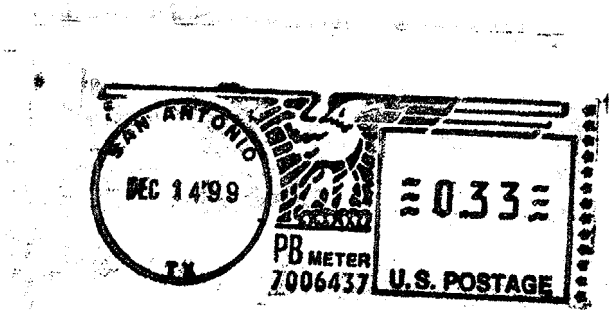

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